

Measurement of Intra-sac Pressure in an Aneurysm Following EVAR

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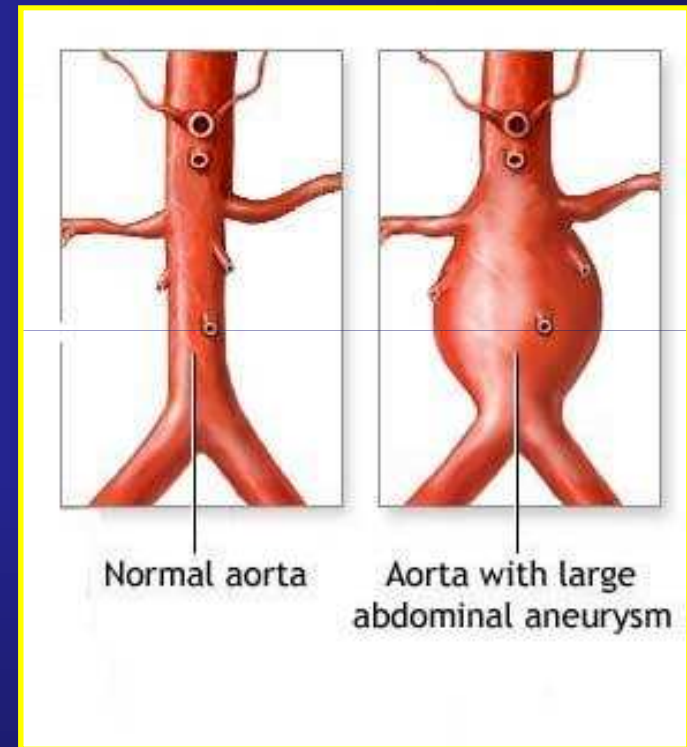
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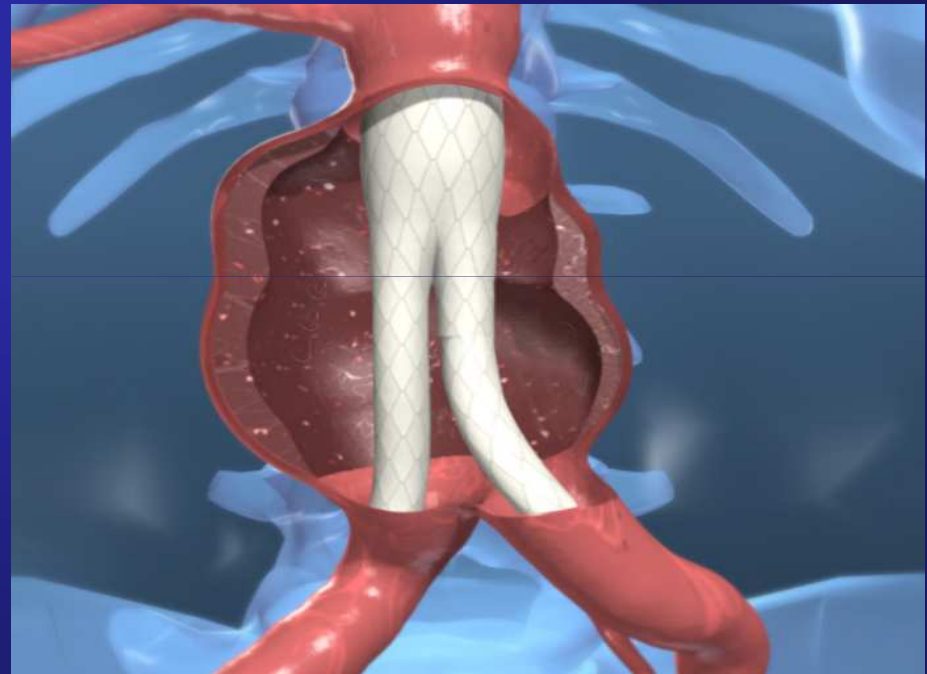
Aortic Aneurysms

- Occur when a weak area of the aorta expands or bulges
 - Abdominal Aortic Aneurysm (AAA)
 - Thoracic Aortic Aneurysm (TAA)
- ~65,000 aneurysms repaired annually
- Two potential treatments
 - Open repair
 - Endovascular aneurysm repair
 - EVAR
 - TEVAR



Endovascular Aneurysm Repair (EVAR)

- EVAR accounts for the majority of aneurysm repair surgeries
 - Decreased complications / morbidity vs. open surgical repair
- Potential EVAR complications
 - Endoleaks
 - Graft migration



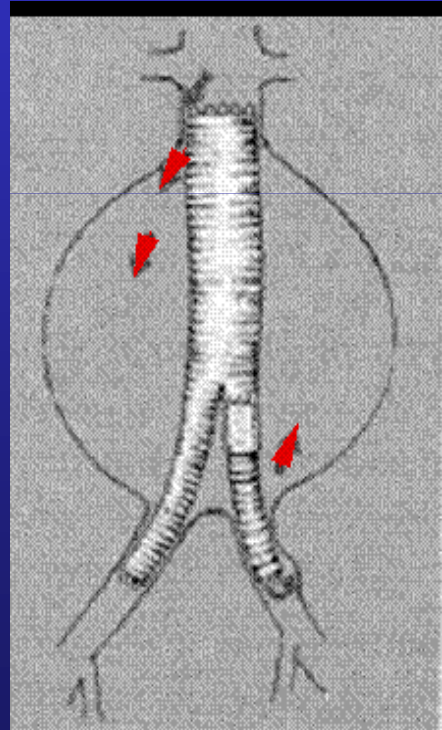
Endoleaks – The Challenge

Inadequate
Seal

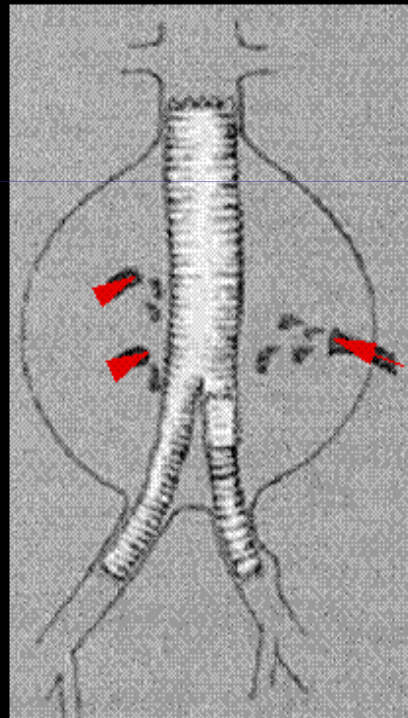
Collateral
Vessel

Dislodged or
Torn Limb

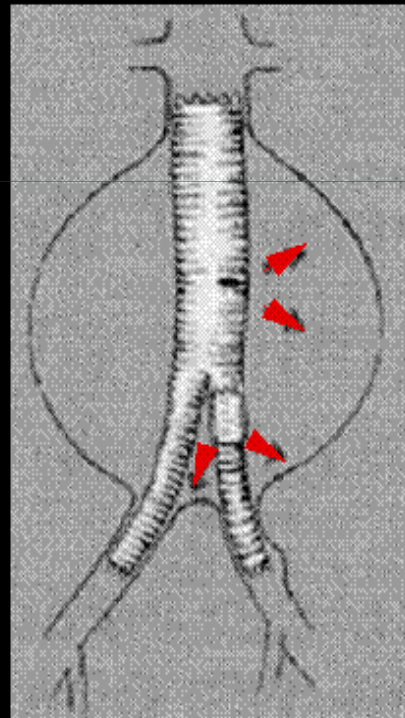
Fabric Weeping



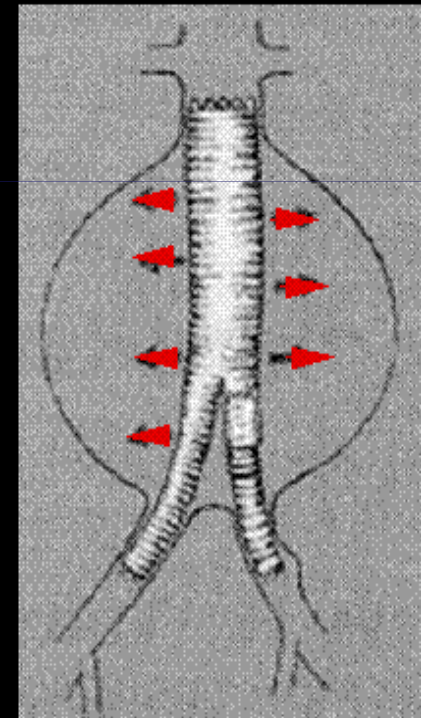
Type 1



Type 2

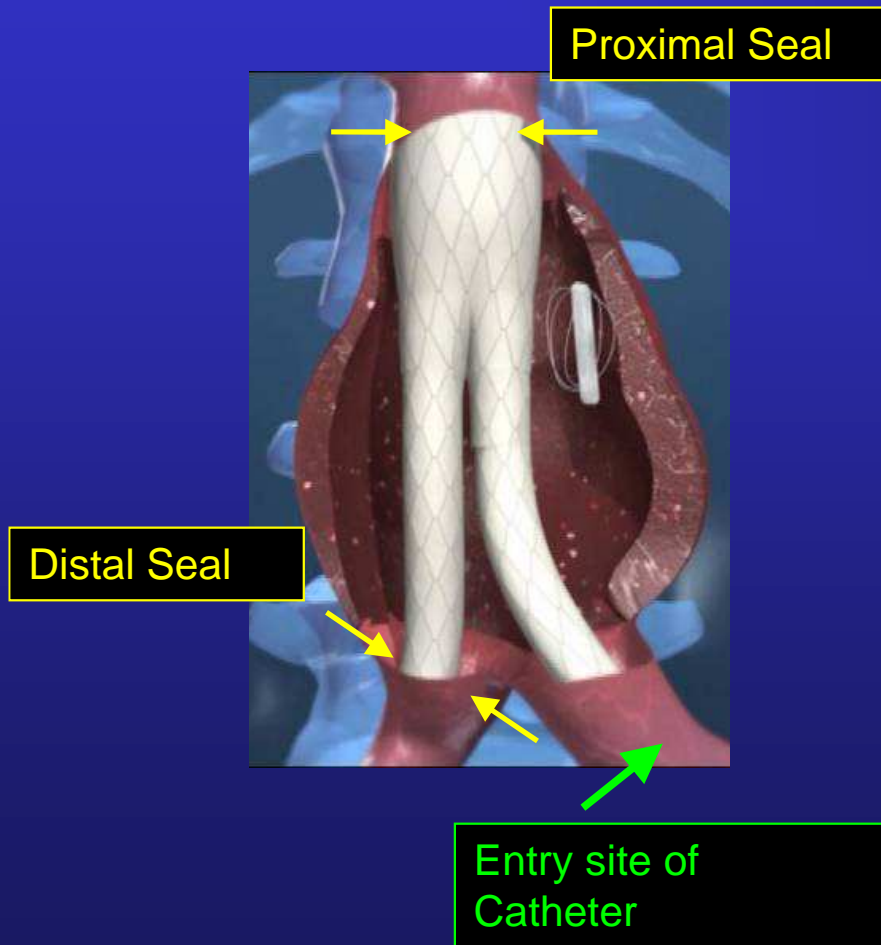


Type 3



Type 4

Wireless pressure sensors were recently introduced to help identify successful aneurysm exclusion following endovascular aneurysm repair (EVAR).

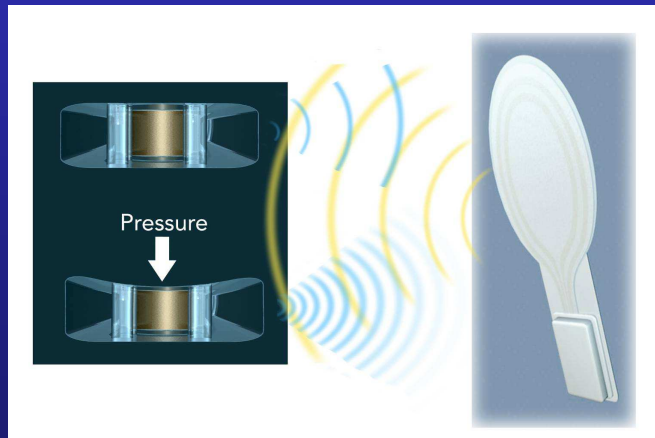


- Cleared by FDA in November, 2005
- Angiography/CTA provide images which are not definitive about the existence, location or type of leak
 - Safety – radiation, contrast toxicity
 - Cost
 - Inconvenience (every 6 months)
- Measuring sac pressure provides evidence for successful aneurysm exclusion which should translate into long-term graft stability^{1,2}

¹Treharne, et al., 1999

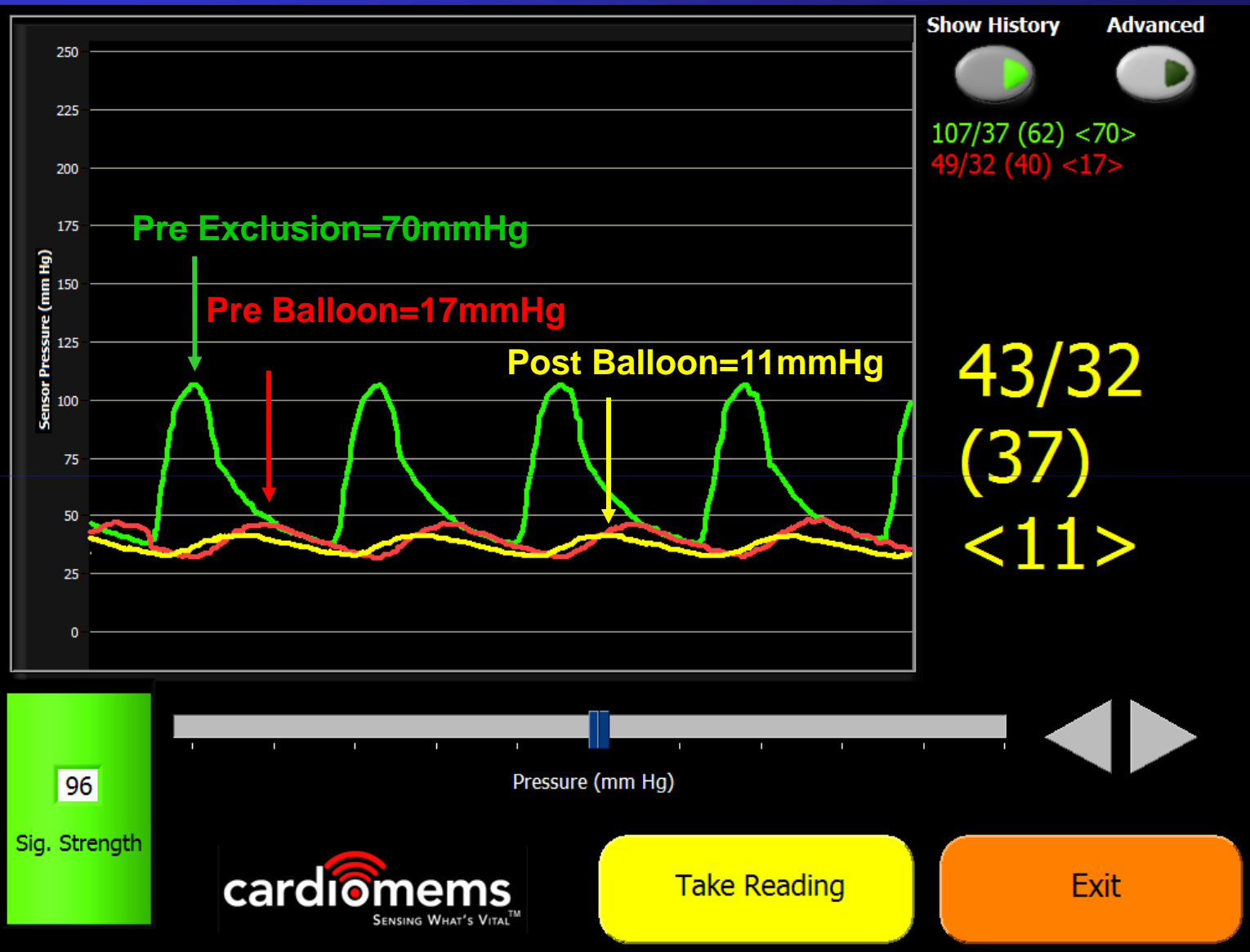
²Dias et al., 2004

Intra-arterial pressure sensor and electronic monitoring equipment



Measuring Intra-Sac Pressure

- Intra-arterial pressure sensors are indicated for measuring intra-sac pressure during endovascular abdominal aortic aneurysm (AAA) repair or thoracic aortic aneurysm (TAA) repair
- Pressure readings taken during the EVAR procedure:
 - Pre-exclusion
 - Post-exclusion



Patient Selection Criteria

- Currently, EVAR patients with higher risk anatomy or concern after deployment of the main body device
- As better data is collected, a broader indication may be reasonable

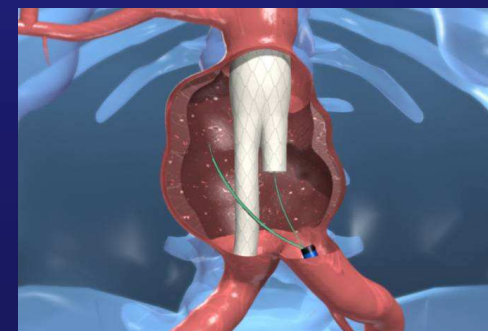
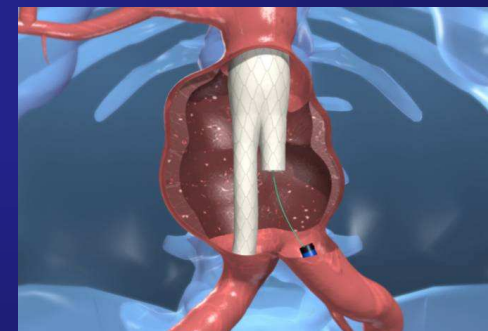
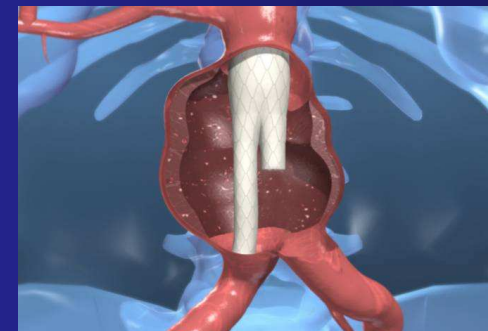
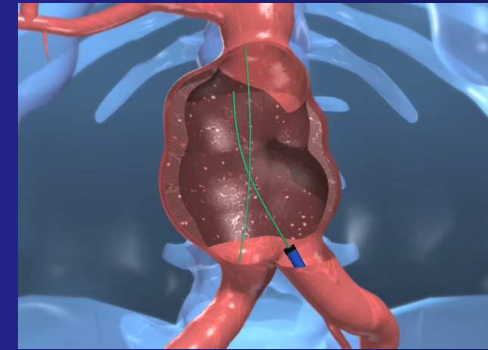
Surgical placement of pressure measurement sensor

- Two potential approaches
 - Contralateral (recommended)
 - Ipsilateral
- Determined by endograft type, patient anatomy, vessel conditions, etc.



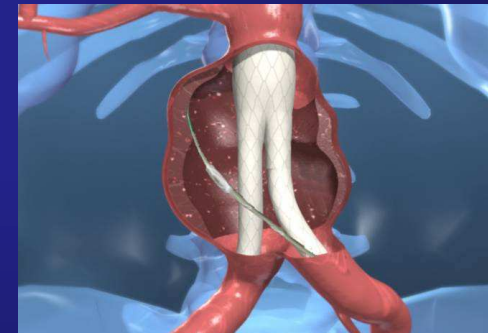
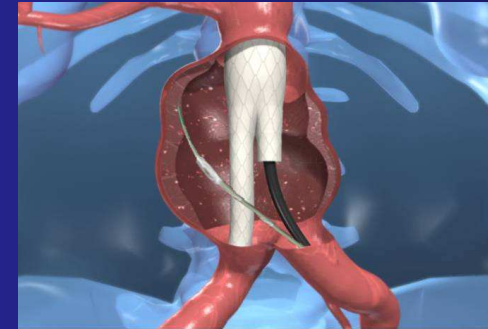
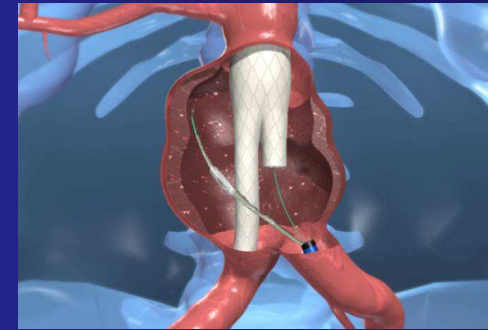
Recommended surgical approach

- Attain bilateral guidewire access.
- Insert main body of stent graft.
- Insert sheath on contralateral side.
- Use wire to locate gate.
- Insert additional wire through contralateral sheath next to gate wire and advance into sac.



Recommended surgical approach

- Insert sensor over guidewire through contralateral sheath and advance into sac.
- Calibrate sensor and take first reading.
- Remove contralateral sheath over sensor catheter and gate wire, maintaining sensor position.
- Introduce contralateral graft limb (or limb delivery sheath) over gate wire.
- Deploy contralateral limb and fix graft.
- Take final sensor reading.
- Confirm sensor position, release sensor and remove sensor delivery catheter.



Key Documentation Points

Physician includes in dictation:

- Procedure performed in operating room
- Placement of pressure measurement sensor
- Use of external electronic monitoring equipment to measure pressure/verify appropriate placement of graft

Data Issues

- Lack of specific ICD-9-CM codes for placement of a pressure measurement sensor and monitoring intra-arterial pressure during endovascular repair of an aneurysm creates ongoing data issues:
 - Inability to track procedures clearly in the encoded data
 - Inability to differentiate EVAR procedures that use pressure measurement sensors
 - Inability to review and analyze data specific to these procedures

Questions?

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Thank you.